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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,073	04/16/2001	Asim Dasgupta	220002054822	5718

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/13/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/836,073

Applicant(s)

DASGUPTA ET AL.

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a polypeptide of designated formula (see claim 1), classifiable in class 530, subclass 326.
- II. Claims 13-19, drawn to nucleic acid, vectors , host cells and a method of use, classifiable in class 435, subclass 69.1.
- III. Claims 20-24, drawn to a method of treatment of viral infection via administration of a polypeptide, classifiable in class 514, subclass 2.
- IV. Claims 25-30, drawn to treatment of viral infection via a nucleic acid based therapy, classifiable in class 514, subclass 44.
- V. Claim 31, drawn to a method of selective delivery of a compound to the liver, classifiable in class 514, subclass 13.
- VI. Claims 32-35, drawn to antibodies and methods of use, classifiable in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acids of Group II could be used to make the polypeptide of Group I, however the polypeptide of group I could be made by a materially different process such as by chemical synthesis.

Art Unit: 1635

Inventions I and (IV and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related since the methods of group IV is drawn to a nucleic acid based therapy and the invention of group VI is drawn to antibodies and a method of use thereof, and the invention of Group I is drawn to a polypeptide which is not a nucleic acid or an antibody and is not interchangeable in the steps of the methods of Groups IV and VI, for example.

Inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods that require different method steps using materially different components and may result ends or achieve the same end via the use of non-interchangeable components and method steps, for example.

Inventions I and (III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Groups III and V can be performed using different compounds. For example the method

of group III could be performed using known antiviral compounds and the method of group VI could be performed by using other liver specific ligands, for example.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

Application/Control Number: 09/836,073

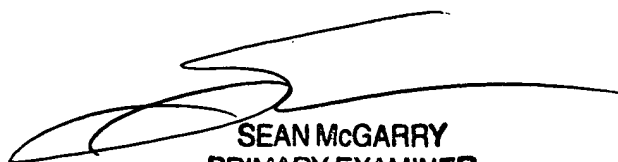
Page 5

Art Unit: 1635

308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

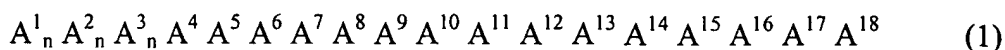
SRM  
February 11, 2003



**SEAN MCGARRY**  
**PRIMARY EXAMINER**  
1635

Claims

1. A compound of the formula



and acylated and/or amidated forms thereof,

wherein each n is independently 0 or 1;

$A^1$ ,  $A^2$ , and  $A^3$  are each independently any amino acid;

$A^4$ ,  $A^{12}$ , and  $A^{17}$  are independently acidic amino acids;

$A^{13}$ ,  $A^{14}$ ,  $A^{15}$ , and  $A^{18}$  are independently aromatic amino acids;

$A^5$ ,  $A^7$ ,  $A^8$ ,  $A^{11}$ , and  $A^{16}$  represent any amino acid;

$A^6$ ,  $A^9$ , and  $A^{10}$  represent independently a basic amino acid or a polar neutral amino acid;

wherein each of said amino acids may be in the L form, racemic form, or D form.

2. The compound of claim 1 wherein all amino acids are gene encoded.

3. The compound of claim 1 wherein all linkages between  $A^i$  subunits are amide linkages.

4. The compound of claim 1 where all of  $A^i$  are in the D form.

5. The compound of claim 1 wherein all of  $A^i$  are in the L form.

6. The compound of claim 1 wherein each of  $A^4$ ,  $A^{12}$  and  $A^{17}$  is independently aspartic or glutamic.

7. The compound of claim 1 wherein each of  $A^{13}$ ,  $A^{14}$ ,  $A^{15}$  and  $A^{18}$  is independently phenylalanine or tyrosine.

8. The compound of claim 1 wherein  $A^8$  is cysteine.

9. The compound of claim 1 wherein each of A<sup>6</sup>, A<sup>9</sup> and A<sup>10</sup> is independently lysine, histidine, arginine, glutamine, or asparagine.

10. The compound of claim 1 which is selected from the group consisting of AALEAQICQQIEYYFGDF, AALQAKICHQIQYYFGQF, QQQEAKICHQIEYYFGDF and AALEAKICHQIEYQFGDF.

11. The compound of claim 1 which is in isolated or purified form and is selected from the group consisting of ALEAKICHQIEYYFGDF, AALEAKICHQIEYYFGDF, LDLDTKICEQIEYYFGDF, AALEAKICHQIEYYFGDF, DDADQRNIKQLEYYFGNI, VSKLEASTIRQEYYFGDA and QERAIIRQVEYYFGDF.

12. A pharmaceutical, veterinary or agricultural/horticultural composition which comprises the compound of claim 1 along with a suitable excipient.

13. A nucleic acid molecule comprising a nucleotide sequence encoding the compound of claim 2.

14. A recombinant expression system comprising a nucleotide sequence encoding the compound of claim 2 operably linked to control sequences effective for its expression.

15. A recombinant host cell modified to contain the expression system of claim 14.

16. The recombinant host cell of claim 15 wherein said expression system is integrated into the genome of said host cell.

17. A method to produce the compound of claim 2, which method comprises effecting expression of said compound from the expression system of claim 14.

18. The expression system of claim 14 which is included in a viral vector.

19. The viral vector of claim 18 which is an adenoviral vector or a retroviral vector.

20. A method to treat viral infection in a plant or animal subject which method comprises administering to said subject an antivirally effective amount of the compound of claim 1.

21. The method of claim 20 wherein said method further comprises administering at least one additional antiviral agent.

22. The method of claim 21 wherein said administering of the compound and said at least one additional antiviral agent is substantially simultaneous.

23. The method of claim 21 wherein said administering of the compound of claim 1 and said at least one antiviral compound is sequential.

24. The method of claim 21 wherein said additional antiviral compound is I-RNA.

25. A method to treat viral infection in a plant or animal subject, which method comprises administering to said subject an antivirally effective amount of a nucleotide sequence encoding the compound of claim 2.

26. The method of claim 25 wherein said nucleotide sequence is comprises in an expression system compatible with the cells of said subject.

27. The method of claim 25 wherein said method further comprises administering at least one additional antiviral agent.

28. The method of claim 27 wherein said administering of the compound and said at least one additional antiviral agent is substantially simultaneous.

29. The method of claim 27 wherein said administering of the compound of claim 1 and said at least one antiviral compound is sequential.

5 30. The method of claim 27 wherein said additional antiviral compound is I-RNA.

31. A method to deliver a compound selectively to the liver, which method comprises administering to a subject containing a liver a desired compound coupled to the compound of claim 1.

10 32. Antibodies specifically immunoreactive with the compound of claim 1.

33. The antibodies of claim 32 which are immunospecific fragments.

34. The antibodies of claim 33 which are monoclonal antibodies.

15 35. A method to purify the compound of claim 1, which method comprises contacting a sample containing said compound with antibodies specifically immunoreactive therewith, said antibodies coupled to a solid support.